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Methimazole Tablets

DEFINITION

Methimazole Tablets contain NLT 94.0% and NMT 106.0% of the labeled amount of methimazole ($C_4H_6N_2S$).

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

Sample: Digest a quantity of powdered Tablets, equivalent to 10 mg of methimazole, with 10 mL of warm chloroform for 20 min, filter, and evaporate the filtrate on a steam bath to dryness.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 120 mg of methimazole, to a 100-mL volumetric flask. Add about 80 mL of water, insert the stopper, and shake by mechanical means or occasionally by hand for 30 min. Dilute with water to volume, and filter.

Analysis: Add 3.5 mL of 0.1 N sodium hydroxide VS to 50.0 mL of *Sample solution*, mix, and add, with stirring, 7 mL of 0.1 N silver nitrate. Continue the titration with the 0.1 N sodium hydroxide VS, determining the end-point potentiometrically. Each mL of 0.1 N sodium hydroxide is equivalent to 11.42 mg of methimazole ($C_4H_6N_2S$).

Acceptance criteria: 94.0%–106.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 500 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution: USP Methimazole RS at a known concentration in *Medium*

Sample solutions: Filtered solution under test, suitably diluted with *Medium*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 252 nm

Tolerances: NLT 80% (*Q*) of the labeled amount of methimazole ($C_4H_6N_2S$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

Procedure for content uniformity

Standard solution: 5 µg/mL of USP Methimazole RS in water

Sample stock solution: Place 1 Tablet, previously crushed or finely powdered, in a 100-mL volumetric flask. Add 50 mL of water, and shake by mechanical means for 30 min. Dilute with water to volume, mix, and filter, discarding the first 20 mL of filtrate.

Sample solution: Nominally 5 µg/mL of methimazole in water from *Sample stock solution*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 252 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of the labeled amount of methimazole ($C_4H_6N_2S$) in the Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Methimazole RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of methimazole in the *Sample solution* (µg/mL)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers.
- **USP Reference Standards** ⟨11⟩
  USP Methimazole RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METHIMAZOLE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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